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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/481,990	01/11/2000	Florian Lesage	989.6351DIV	6424

35811 7590 05/23/2003

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EXAMINER

LANDSMAN, ROBERT S

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/481,990

Applicant(s)

LESAGE ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 14-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Formal Matters

- A. Amendment C, filed 3/11/03, has been entered into the record.
- B. Claims 1-12 and 14-26 are pending in the application. Claims 13 has been cancelled and claims 1-10 and 14-26 are drawn to non-elected inventions. Therefore, claims 11 and 12 are the subject of this Office Action.
- C. All Statutes not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. All objections to the specification have been withdrawn in view of Applicants' amendments.

3. Claim Objections

- A. The objection to claims 11 and 12 has been overcome since Applicants have amended claim 11 to recite "an isolated."

4. Double Patenting

- A. Claims 11 and 12 remain provisionally rejected applications 09/436,265; 09/939,483; 09/939,484; 09/892,360. Applicants have acknowledged these rejections and stated that they be held in abeyance until allowable subject matter is identified. However, since many of these provisional rejections were not, in fact, made in the previous Office Action, they will be made in this Office Action.

Claims 11 and 12 are directed to an invention not patentably distinct from numerous claims of these commonly assigned applications. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). The commonly assigned applications, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject

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matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

B. Claims 11 and 12 are provisionally rejected under claims 5-14 and 37-40 (all pending claims) of copending application 09/436,265 for the reasons already of record on pages 3-4 of the Office Action dated 8/28/02. The claims of the present invention are drawn to an isolated TWIK-1 protein having 2 pore domains and 4 transmembrane domains, or which comprises SEQ ID NO:2 or a functionally equivalent derivative thereof. The claims of copending application 09/436,265 recite potassium channel proteins having 2 pore domains and 4 transmembrane domains which are located in various organs, and which have various characteristics. Due to the breadth of claims 11 and 12 of the instant application, all the claims of the copending application read on the claims of the instant invention.

C. Claims 11 and 12 are provisionally rejected under claims 9-16 of copending application 09/939,483 for the reasons already of record on pages 4-5 of the Office Action dated 8/28/02. The claims of the present invention are drawn to an isolated TWIK-1 protein having 2 pore domains and 4 transmembrane domains, or which comprises SEQ ID NO:2 or a functionally equivalent derivative thereof. The claims of copending application 09/939,483 recite a potassium channel protein having more than one P domain and 3 or more transmembrane domains, which have specific properties. Due to the breadth of claims 11 and 12 of the instant application, all the claims of the copending application read on the claims of the instant invention.

D. Claims 11 and 12 are provisionally rejected under claims 9-16 of copending application 09/939,484 for the reasons already of record on pages 5-6 of the Office Action dated 8/28/02. The claims of the present invention are drawn to an isolated TWIK-1 protein having 2 pore domains and 4 transmembrane domains, or which comprises SEQ ID NO:2 or a functionally equivalent derivative thereof. The claims of copending application 09/939,484 recite a potassium channel protein having more than one P domain and 3 or more transmembrane domains, which have specific properties. Due to the breadth of claims 11 and 12 of the instant application, all the claims of the copending application read on the claims of the instant invention.

E. Claims 11 and 12 are provisionally rejected under claims 1-3 and 27 of copending application 09/892,360 for the reasons already of record on page 6 of the Office Action dated 8/28/02. The claims of

the present invention are drawn to an isolated TWIK-1 protein having 2 pore domains and 4 transmembrane domains, or which comprises SEQ ID NO:2 or a functionally equivalent derivative thereof. The claims of copending application 09/892,360 recite a potassium channel protein having two P domain and which has specific properties. Due to the breadth of claims 11 and 12 of the instant application, all the claims of the copending application read on the claims of the instant invention.

5. Claim Rejections - 35 USC § 101

A. Claims 11 and 12 remain rejected under 35 USC 101 for the reasons already of record on page 7 of the Office Action dated 8/28/02. Applicants argue that the protein of the present invention has a fundamental role in the transport of potassium in a large number of cells and a deficiency in this protein inhibits proper potassium transport. Applicants argue that the protein can be used to screen for the deficiency of TWIK protein in tissues, indicating a disease state, or propensity to develop a disease state. Applicants also argue that the protein can be used to make antibody to said protein which can then be used to identify cells comprising the protein. The cells can then be used as a tool for testing treatments of cells deficient in the protein.

These arguments have been considered, but are not deemed persuasive. First, though Applicants have identified this protein as a TWIK protein, they have not disclosed the specific functions of this protein which separate it from other known potassium channel proteins. Applicants have not identified any diseases associated with this protein. Therefore, the artisan would not know how to use this protein, other than to transport potassium, which, itself, is not a specific utility. Applicants provided a paper by Wildemann stating the function of TWIK proteins in nervous system pathology. However, a post-filing reference can only be used to support an assertion disclosed in the specification as filed. Applicants did not disclose the teachings of Wildemann in the instant specification. Applicants did not provide any link of the protein of the invention to any specific diseases, or nervous system pathology. The argument that the protein can be used to study disease states, or to make antibody, or to identify cells, is, respectfully, a circular argument. Without knowing the utility of the protein, then the antibodies have no utility. To use antibodies to identify cells which express the protein, or to screen for a TWK deficiency would not be useful without knowing the utility of the protein.

6. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 11 and 12 remain rejected under 35 USC 112 for the reasons already of record on page 8 of the Office Action dated 8/28/02 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

B. Claims 11 and 12 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 8-9 of the Office Action dated 8/28/02. Applicants did not specifically address this argument in their response. However, the Examiner addressed Applicants' arguments under their response to the written description rejection as if they were also intended to address this rejection since the issues are identical in the two rejections under 35 USC 112, first paragraph. Applicants argue that one of ordinary skill in the art would be able to make conservative amino acid substitutions to the protein of SEQ ID NO:2 to produce a functional protein similar to SEQ ID NO:2. Applicants also argue that the TWIK protein of the present invention has a highly conserved P domain and that a comparison of TWIK with the Genbank database allowed identification of 5 potential TWIK homologs.

These arguments have been considered, but are not deemed persuasive. While it is true that Applicants could easily make conservative substitutions to the protein of SEQ ID NO:2, Applicants have not identified the critical amino acids residues which are required to maintain the function of the protein of SEQ ID NO:2. Applicants have shown that one of the P domains is slightly conserved among potassium channels (Figure 2A). However, the breadth of these claims is still excessive since the claims encompass in scope proteins having up to every amino acid conservatively altered. Applicants have not provided any guidance or working examples that this potentially large number of changes can be made to the protein of SEQ ID NO:2 while retaining its specific TWIK functions. In fact, respectfully, Applicants have not provided any guidance or working examples of any functional TWIK proteins other than that of SEQ ID NO:2. Furthermore, the claims are not limited to conservative substitutions since the claims recite "functionally equivalent derivatives." Therefore, any protein with 2 pore domains and 4 transmembranes is encompassed by the claims, regardless of its structure and it is not predictable to the artisan what changes can be made to the protein of SEQ ID NO:2 without affecting its potassium channel function. In addition, the limitation "functionally equivalent modified form" does not require that these derivatives even have to have the 2 pore domains or 4 transmembrane domains, especially in the absence of a functional limitation in the claim.

Therefore, the breadth is excessive with regard to claiming any TWIK-1 protein which has 2 pore domains and 4 transmembrane domains, or functionally equivalent modified forms of SEQ ID NO:2. Furthermore, there is a lack of guidance and working examples of any TWIK protein other than SEQ ID NO:2 as well as a lack of predictability as to what changes can be made to the protein of SEQ ID NO:2 and which would allow it to retain its potassium channel functions. Therefore, the Examiner maintains that undue experimentation would be required to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

7. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 11 and 12 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 9-10 of the Office Action dated 8/28/02. Applicants argue that one of ordinary skill in the art would be able to make conservative amino acid substitutions to the protein of SEQ ID NO:2 to produce a functional protein similar to SEQ ID NO:2. Applicants also argue that the TWIK protein of the present invention has a highly conserved P domain and that a comparison of TWIK with the Genbank database allowed identification of 5 potential TWIK homologs.

These arguments have been considered, but are not deemed persuasive. While it is true that Applicants could easily make conservative substitutions to the protein of SEQ ID NO:2, Applicants have not identified the critical amino acids residues which are required to maintain the function of the protein of SEQ ID NO:2. Applicants have shown that one of the P domains is slightly conserved among potassium channels (Figure 2A). However, the claims encompass proteins having up to every amino acid conservatively altered. Applicants have not provided adequate written description demonstrating that this potentially large number of changes can be made to the protein of SEQ ID NO:2 while retaining its specific TWIK functions. In fact, respectfully, Applicants have not provided adequate written description of any functional TWIK1 proteins other than that of SEQ IDNO:2. Furthermore, the claims are not limited to conservative substitutions since the claims recite “functionally equivalent derivatives” of SEQ ID NO:2. Therefore, any protein with 2 pore domains and 4 transmembranes is encompassed by the claims, regardless of its structure. In addition, the limitation “functionally equivalent modified form” does not require that these derivatives even have to have the 2 pore domains or 4 transmembrane domains, especially in the absence of a functional limitation in the claim. It is believed that all pertinent arguments have been addressed.

8. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the term "TWIK1." However, this is an acronym. The claim recites that this protein must have at least 2 pore domains and 4 transmembrane domains. However, the term "TWIK1" is vague and indefinite and the metes and bounds of what constitutes a TWIK protein is not known, other than for the two limitations. Therefore, it would not be clear to the artisan when they can conclude they have a TWIK1 protein simply by identifying a protein with 2 pore domains and 4 transmembrane domains.

9. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Ketchum et al. This rejection was previously withdrawn based on Applicants' arguments on pages 4-5 of Paper No 7, filed 6/22/01. Applicants argued that the protein of Ketchum et al. has 2 pore domains and 8 transmembrane domains. However, present claim 11 is "open language" since it recites "having." Therefore, the protein of Ketchum "has" 2 pore domains and 4 transmembrane domains since, in order to have 8 transmembrane domains, one must have 4, since 8 comprises (i.e. have) 4.

10. Conclusion

A. No claim is allowable.

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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
May 21, 2003



**ROBERT LANDSMAN
PATENT EXAMINER**